REMARKS

I. STATUS OF THE CLAIMS

Claims 42-55 and 60-64 were pending at the time of the Action. Claims 42, 46, 53-55 and 61-64 are amended and claim 65 is new. The amendments are mostly of an editorial nature and support therefore can be found in the specification and in the claims as originally filed. In brief, the hybridization language which remains (claims 42 (iv-vi) and 62) is found in the context of one of the mutations identified by the Applicants. Support for new claim 65 can be found for example in claim 42 as previously filed.

Applicants note that the Examiner considers the method claims comprising the mutant sequences recited in claims 62-64 as allowable if recited in independent form.

No new matter has been entered by way of the instant amendment. Claims 42-55 and 60-65 are pending and under examination.

II. REJECTIONS UNDER 35 USC § 102

The Action rejects claims 42-55 and 60-64 as allegedly being anticipated by Noda (1987). Applicants traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claims 42-55 and 60-64 are patentable over Noda

As stated above, in order to be anticipatory, a reference must teach all of the claim limitations. In particular the Examiner objects to (iii) of claim 42 ("... SCN1A protein having

sodium channel activity and encoded by an SCN1A nucleic acid sequence having at least 95% identity to the nucleic acid set forth in SEQ ID NO:1 or 2"). In view of the deletion of this expression from (iii), the Examiner's rejection has been rendered moot. Applicants advise that the "95% identity" recitation rejected by the Examiner while deleted from (iii) is nonetheless present in (iv)-(vi). However, since the Examiner considers that the mutant sequences are novel (and non-obvious) and since the 95% identity recitation is found together with the presence of the novel (and inventive) mutations, Applicants respectively submits that the claimed limitations are not taught by Noda. Applicants further note that the current claims are directed to human SCN1A sequences that are distinct from the rat sequences described by Noda.

In view of the above, Applicants respectfully request that the rejection under 35 U.S.C. 102(b) in view of Noda be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. §103

The Action rejects **(A)** claims 42-51, 53, and 60-61 as allegedly being obvious over Noda in view of Hartshorne; **(B)** claims 42-47, 49-53, and 60-61 as allegedly being obvious over Noda in view of Kienle; **(C)** claims 42-47, 49-51, 53-54, and 60-61 as allegedly being obvious over Noda in view of Wood, Malo, and Current Protocols in Molecular Biology; and **(D)** claims 42-47, 49-51, 53-55, and 60-61 as allegedly being obvious over Noda in view of Wood, Malo, and Current Protocols in Molecular Biology and further in view of Avanzini and Soares. Applicants traverse.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicants note that if an independent claim is not obvious then

claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). Accordingly, with claim 42 being non-obvious, as described below, then those claims depending from claim 42 are also non-obvious.

A. Claims 42-51, 53, and 60-61 are patentable over Noda in view of Hartshorne

Claims 42-51, 53, and 60-61 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Noda in view of Hartshorne. In order "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. As set forth above and incorporated here by reference, and as acknowledged by the Examiner, Noda fails to disclose the claimed SCN1A sequences (including the mutant sequences comprising one of the three described mutations or sequences having 95% identity to such sequences comprising the claimed mutations) and a method for the identification of a test compound that modulates SCN1A activity. Similarly, while Hartshorne teaches the purification of sodium channels it fails to disclose or suggest the claimed recombinantly expressed SCN1A protein. In addition it is impossible from Hartshorne to know which sodium channel has been purified. Therefore, the combination of Noda and Hartshorne fails to disclose or suggest every element of the claimed invention.

B. Claims 42-47, 49-53, and 60-61 are patentable over Noda in view of Kienle

Claims 42-47, 49-53, and 60-61 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Noda in view of Kienle. The combination of Noda and Kienle fail to disclose or suggest every element of the claimed invention. The defects of Noda are not remedied by Kienle, a technique-driven article, which teaches a peptide functionalized substrate and its use in receptor ligand (i.e., antibody) analyses.

C. Claims 42-47, 49-51, 53-54, and 60-61 are patentable over Noda in view of Noda in view of Wood, Malo, and Current Protocols in Molecular Biology

Claims 42-47, 49-51, 53-54, and 60-61 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Noda in view of Wood, Malo, and Current Protocols in Molecular Biology. The combination of Noda in view of Wood, Malo, and Current Protocols in Molecular Biology fail to disclose or suggest every element of the claimed invention. Applicants note that it is well settled that a method for isolating a nucleic acid sequence in combination with what was well known to one skilled in the art is insufficient in establishing the sequence of a DNA. The DNA sequence is not established until the DNA is in fact isolated. See *Fiers v. Revel*, 984 F.2D 1164, 1168 (Fed. Cir. 1993) citing *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991). Furthermore, *KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007),* is often cited for the proposition that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.". The passage above in KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. In this case, the ordinarily skilled artisan would have to have some reason to select (among an outrageous number of unpredictable alternatives) the DNA sequence that produced the human SCN1A protein. Clearly, having a fragment of a gene and extrapolating to an isolated full length coding sequence is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness. *Id. at 1742. -- Ortho-McNeil Pharmaceutical Inc. v Mylan Pharmaceutical Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Thus, the defects of Noda are not remedied by Wood which as the Examiner states "While Wood teaches these methods relating to sodium channels expressed in the periphery, the

reference does not explicitly teach sodium channels encoded by nucleic acids at least 95% identical to SEQ ID NO:3..." (emphasis added). The defects of Noda are not remedied by Malo which teaches, as stated by the Examiner, "the human sequence is obviously only a partial sequence" (emphasis added). How is one of skill to extrapolate, without the use of hindsight based on the current disclosure, the complete human sequence? Finally, the defects of Noda are not remedied by Current Protocols in Molecular Biology which teaches "how to screen a cDNA library to obtain clones". The defects of Noda are not remedied by a combination of any one of Wood, Malo, and Current Protocols in Molecular Biology. The combination does not disclose or suggest every element of the claimed invention.

D. Claims 42-47, 49-51, 53-55, and 60-61 are patentable over Noda in view of Noda in view of Wood, Malo, Current Protocols in Molecular Biology and further in view of Avanzini and Soares.

Claims 42-47, 49-51, 53-55, and 60-61 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Noda in view of Wood, Malo, Current Protocols in Molecular Biology and further in view of Avanzini and Soares. The combination of Noda in view of Wood, Malo, and Current Protocols in Molecular Biology, and further in view of Avanzini and Soares fail to disclose or suggest every element of the claimed invention. The reasons why Wood, Malo, and Current Protocols in Molecular Biology do not overcome the defects of Noda have been mentioned in "**C.**", above. The further consideration of Avanzini and Soares does not remedy the defects of these combinations. Avanzini using coronal slices of sensimotor cortex prepared from immature rats fails to remedy the deficiency of Noda alone or together with the other references. Soares "which does not explicitly teach nucleic acids encoding sodium channels and does not teach screening assays" (emphasis added) teaches cDNA libraries from neonatal infant brain. Thus, once again, these combinations do not disclose or suggest every element of the claimed invention.

In view of the above, Applicants respectfully request the withdrawal of all obviousness rejections.

IV. CONCLUSION

Applicants believe that the present document is a full and complete response to the Action dated May 6, 2008. Applicants respectfully believe that the instant amendment places the instant application in condition for allowance and a Notice to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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